

Image Description: Administration for Community Living

**Administration for Community Living**

National Institute on Disability, Independent Living, and Rehabilitation Research

HHS/ACL/NIDILRR: Small Business Innovation Research Program (SBIR) Phase I

HHS-2016-ACL-NIDILRR-BI-0142

Application Due Date: 04/25/2016

HHS/ACL/NIDILRR: Small Business Innovation Research Program (SBIR) Phase I

HHS-2016-ACL-NIDILRR-BI-0142

TABLE OF CONTENTS

- I. [Funding Opportunity Description](#)
- II. [Award Information](#)
- III. [Eligibility Information](#)
  - 1. Eligible Applicants
  - 2. Cost Sharing or Matching
  - 3. Responsiveness and Screening Criteria
- IV. Application and Submission Information
  - 1. [Address to Request Application Package](#)
  - 2. [Content and Form of Application Submission](#)
  - 3. [Submission Dates and Times](#)
  - 4. [Intergovernmental Review](#)
  - 5. [Funding Restrictions](#)
  - 6. [Other Submission Requirements](#)
- V. [Application Review Information](#)
  - 1. Criteria
  - 2. Review and Selection Process
  - 3. Anticipated Announcement Award Date
- VI. [Award Administration Information](#)
  - 1. Award Notices
  - 2. Administrative and National Policy Requirements
  - 3. Reporting
  - 4. FFATA and FSRS Reporting
- VII. [Agency Contacts](#)
- VIII. [Other Information](#)

**Department of Health & Human Services**  
**Administration for Community Living**

**ACL Center:** National Institute on Disability, Independent Living, and Rehabilitation Research

**Funding Opportunity Title:** HHS/ACL/NIDILRR: Small Business Innovation Research Program (SBIR) Phase I

**Announcement Type:** Initial

**Funding Opportunity Number:** HHS-2016-ACL-NIDILRR-BI-0142

**Primary CFDA Number:** 93.433

**Due Date For Letter of Intent:** **03/30/2016**

**Due Date for Applications:** **04/25/2016**

**Date for Informational Conference** **03/16/2016**

**Call:**

Applications that fail to meet the application due date will not be reviewed and will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or, with <http://www.grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful submission.

### **Executive Summary**

The Administrator of the Administration for Community Living invites applications for new awards for fiscal year (FY) 2016 for NIDILRR's **Small Business Innovation Research (SBIR)** Program (CFDA 93.433). All SBIR projects funded by NIDILRR must address the needs of individuals with disabilities (see 29 U.S.C. 760). The scientific and technical merit of the proposed research/research and development (R/R&D) is the primary concern for all projects supported by NIDILRR.

### **I. Funding Opportunity Description**

NIDILRR's mission is to generate new knowledge and to promote its effective use to improve the abilities of individuals with disabilities to perform activities of their choice in the community and to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities. All SBIR projects funded by NIDILRR must address the needs of individuals with disabilities (see 29 U.S.C. 760). An application to NIDILRR's SBIR program must support this mission and should present a sound approach to the investigation of an important technological, engineering, or scientific question that it is worthy of support under the stated criteria of this program announcement. The applicant should review the program announcement carefully to ensure that information and data essential for evaluation are included. The scientific and technical merit of the proposed research and research and development (R/R&D) is the primary concern for all research supported by NIDILRR.

The application's R/R&D must be responsive to NIDILRR's SBIR program objectives, and it should also serve as the basis for technological innovation, new commercial products, and processes or services that may benefit the public. Applications must be confined principally to advanced concepts in assistive technologies, scientific, or engineering R/R&D.

**A firm must not propose market research, patent applications, or litigation. Where necessary, the**

**research may be carried out through construction and evaluation of a laboratory prototype.**

The purpose of the Federal SBIR program is to stimulate technological innovation in the private sector and strengthen the role of small business in meeting Federal research or research and development (R/R&D) needs. The specific purpose of NIDILRR's SBIR program is to increase the commercial application of NIDILRR-supported research results and improve the return on investment from NIDILRR-funded research for economic and social benefits to the nation, especially to individuals with disabilities.

An applicant should consult NIDILRR's Long-Range Plan for Fiscal Years 2013-2017 ([78 FR 20299](#)) (the Plan) when preparing its application. The Plan is organized around the following outcome domains: (1) community living and participation; (2) health and function; and (3) employment. In concert with the balance principle described in the Plan, applicants for these SBIR projects must specify in their abstract and project narrative which of NIDILRR's major outcome domains of individual well-being their proposed project will focus on: (1) community living and participation, (2) health and function, or (3) employment. Although applicants may propose projects that address more than one domain, they should select the primary domain addressed in their proposed project.

Applicants may address any topic that supports NIDILRR's mission as described above. For FY 16, there are several invitational priorities of interest to the agency (see below). We do not give an application that meets one of these invitational priorities a competitive or absolute preference over other applications.

1. NIDILRR seeks to enhance opportunities for individuals with disabilities of all types to engage in employment. One barrier to this goal identified by our partners at the U.S. Department of Labor's Office of Disability Employment Policy (ODEP) is the lack of accessibility of technologies used by employers in all aspects of recruiting and hiring, including online job applications and pre-employment testing. Therefore, NIDILRR is particularly interested in SBIR applications that focus on making the processes of reading, understanding, accessing, and completing online job applications and pre-employment tests accessible to people with all types of disabilities.
2. Increased independence of individuals with disabilities in community settings, including educational settings, through the development of technology to support access to these settings and promote integration of individuals with disabilities.
3. Enhanced sensory or motor function of individuals with disabilities through the development of technology to support improved functional capacity.
4. Enhanced workforce participation through the development of technology to increase access to employment, promote sustained employment, and support employment advancement for individuals with disabilities.
5. Enhanced community living and participation for individuals with disabilities through the development of accessible information technology including cloud computing, software, systems, and devices that promote access to information in educational, employment, and community settings, and voting technology that improves access for individuals with disabilities.
6. Improved health-care interventions and increased use of related resources through the development of technology to support independent access to community health-care services for individuals with disabilities.

Applicants should describe the approaches they expect to use to collect empirical evidence demonstrating the effectiveness of the technology they are proposing. This empirical evidence should facilitate the assessment of the efficacy and usefulness of the technology. Technology, science, and engineering firms with strong research capabilities in any of the priority areas listed in this notice are encouraged to participate. Consultative or other arrangements between these firms and universities or other nonprofit organizations are permitted, but the small business concern must serve as the grantee. For Phase I projects, at least two-thirds of the research or analytic activities must be performed by the small business concern grantee.

Note: NIDILRR encourages all applicants to adhere to universal design principles and guidelines. The term “universal design” is defined as “the design of products and environments to be usable by all people, to the greatest extent possible, without the need for adaptation or specialized design” (The Center for Universal Design, 1997). Universal design of consumer products minimizes or alleviates barriers that reduce the ability of individuals with disabilities to effectively or safely use standard consumer products. (For more information: [www.trace.wisc.edu/docs/consumer\\_product\\_guidelines/consumer.pcs/disabil.htm](http://www.trace.wisc.edu/docs/consumer_product_guidelines/consumer.pcs/disabil.htm)).

The three phases of the SBIR program are:

**PHASE I** – Phase I is intended to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR program. The application should concentrate on research that will significantly contribute to proving the scientific or technical feasibility of the approach or concept, a prerequisite to further ACL support in Phase II. Applications are evaluated by panels of expert reviewers based on criteria published in this program announcement. Awards are for periods up to six months. The maximum award amount includes both direct and indirect costs and any reasonable profit/fee requested.

**PHASE II** – Phase II is intended to expand on the results of and to further pursue the development of Phase I projects. Phase II is the principal research or R&D effort. It requires a more comprehensive application, outlining the effort in detail including its commercial potential. All Phase I awardees with approaches that appear sufficiently promising are eligible to apply for Phase II. Once again, applications are evaluated based on published criteria by panels of experts.

Awards are for periods up to two years. The maximum award amount includes both direct and indirect costs and fee. Applicants are allowed the option to distribute the funding for the two-year performance period in equal amounts for each budget period or to request an alternative distribution of funds. The second year of the award will be approved contingent upon submission of an annual performance report and the demonstration of adequate progress in the first year.

**PHASE III** – In Phase III, the small business must use non-SBIR capital to pursue commercial applications of the research or research and development. Also, under Phase III, Federal agencies may award non-SBIR follow-on funding for products or processes that meet the needs of those agencies. NIDILRR does not presently participate in Phase III.

Please review the definitions relevant to this program:

## **Definitions**

The Small Business Administration (SBA) developed the following definitions relevant to the Small Business Innovation Research (SBIR) Program:

### **Act**

The Small Business Act (15 U.S.C. 631, et seq.), as amended.

### **Applicant**

The organizational entity that qualifies as an SBC at all pertinent times and that submits a contract proposal or a grant application for a funding agreement under the SBIR Program.

### **Affiliate**

This term has the same meaning as set forth in 13 CFR Part 121 - Small Business Size Regulations, §121.103 (available at <https://www.sba.gov/content/affiliation>).

### **Awardee**

The SBC receiving an SBIR funding agreement.

### **Commercialization**

The process of developing products, processes, technologies, or services and the production and delivery (whether by the originating party or others) of the products, processes, technologies, or services for sale to or use by the Federal government or commercial markets.

### **Cooperative Agreement**

A financial assistance mechanism used when substantial Federal programmatic involvement with the awardee during performance is anticipated by the issuing agency. The Cooperative Agreement contains the responsibilities and respective obligations of the parties.

### **Covered Small Business Concern**

A small business concern that:

(1) Was not majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms on the date on which it submitted an application in response to a solicitation under the SBIR program; and (2) Is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms on the date of the SBIR award.

### **Essentially Equivalent Work**

Work that is substantially the same research, which is proposed for funding in more than one contract proposal or grant application submitted to the same Federal agency or submitted to two or more different Federal agencies for review and funding consideration; or work where a specific research objective and the research design for accomplishing the objective are the same or closely related to another proposal or award, regardless of the funding source.

### **Extramural Budget**

The sum of the total obligations for R/R&D minus amounts obligated for R/R&D activities by employees of a Federal agency in or through Government-owned, Government-operated facilities.

### **Feasibility**

The practical extent to which a project is capable of being successfully performed.

### **Federal Agency**

An executive agency as defined in 5 U.S.C. §105, and a military department as defined in 5 U.S.C. 102 (Department of the Army, Department of the Navy, Department of the Air Force), except that it does not include any agency within the Intelligence Community as defined in Executive Order 12333, §3.4(f), or its successor orders.

### **Funding Agreement**

Any contract, grant, or cooperative agreement entered into between any Federal agency and any SBC for the performance of experimental, developmental, or research work, including products or services, funded in whole or in part by the Federal Government.

### **Grant**

A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the Federal agency anticipates no substantial programmatic involvement with the awardee during performance.

### **Historically Underutilized Business Zone (HUBZone)**

An SBC meeting the following criteria:

1. Located in a historically underutilized business zone or HUBZone area located in one or more of the following:
  - a) A qualified census tract (as defined in section 42(d)(5)(C)(i)(l) of the Internal Revenue Code of 1986;

b) A qualified non-metropolitan county (as defined in section 143(k)(2)(B) of the Internal Revenue Code of 1986) with a median household income of less than 80 percent of the State median household income or with an unemployment rate of not less than 140 percent of the Statewide average, based on US Department of Labor recent data; or,

c) Lands within the boundaries of federally recognized Indian reservations.

2. Owned and controlled by one or more US Citizens; and,

3. At least 35% of its employees must reside in a HUBZone.

Use the link below to determine if your business is located within a HUBZone:

<http://map.sba.gov/hubzone/maps/>

### **Innovation**

Something new or improved, having marketable potential, including (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies.

### **Intellectual Property**

The separate and distinct types of intangible property that are referred to collectively as "intellectual property," including but not limited to: patents; trademarks; copyrights; trade secrets; SBIR technical data (as defined in this section); ideas; designs; know-how; business, technical and research methods; and other types of intangible business assets, including all types of intangible assets either proposed or generated by an SBC as a result of its participation in the SBIR Program.

### **Joint Venture**

See 13 C.F.R. §121.103(h)

### **Key Individual**

The principal investigator/project manager and any other person named as a "key" employee in a proposal submitted in response to a program solicitation.

### **Manufacturing-Related**

Relating to manufacturing processes, equipment and systems, or manufacturing workforce skills and protection (as defined in Executive Order 13329 available at <http://www.gpo.gov/fdsys/pkg/FR-2004-02-26/pdf/04-4436.pdf>).

### **Program Solicitation**

A formal solicitation for proposals issued by a Federal agency that notifies the small business community of its R/R&D needs and interests in broad and selected areas, as appropriate to the agency, and requests proposals from SBCs in response to these needs and interests. Announcements in the Federal Register or the GPE are not considered an SBIR Program solicitation.

### **Principal Investigator/Project Manager**

The one individual designated by the applicant to provide the scientific and technical direction to the project that will be supported by the funding agreement.

### **Prototype**

A model of something to be further developed, which includes designs, protocols, questionnaires, software, and devices.

### **Research or Research and Development (R/R&D)**

Any activity that is:

1. A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;

2. A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
3. A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

### **SBIR Technical Data**

All data generated in the performance of any SBIR funding agreement.

### **SBIR Technical Data Rights**

The rights an SBC obtains in data generated in the performance of any SBIR funding agreement that an awardee delivers to the Government during or upon completion of a Federally-funded project, and to which the Government receives a license.

### **Small Business Concern**

A concern that meets the requirements set forth in 13 C.F.R. §121.702 (available at [http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&;SID=5027ca4102b15cf57cf8723ff11fc304&;ty=HTML&;h=L&;mc=true&;r=SECTION&;n=se13.1.121\\_1702](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&;SID=5027ca4102b15cf57cf8723ff11fc304&;ty=HTML&;h=L&;mc=true&;r=SECTION&;n=se13.1.121_1702) ).

### **Socially and Economically Disadvantaged Individual**

See 13 C.F.R. §§ 124.103 (available at [http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&;SID=5027ca4102b15cf57cf8723ff11fc304&;ty=HTML&;h=L&;mc=true&;r=SECTION&;n=se13.1.124\\_1103](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&;SID=5027ca4102b15cf57cf8723ff11fc304&;ty=HTML&;h=L&;mc=true&;r=SECTION&;n=se13.1.124_1103)) & 124.104 (available at <http://www.ecfr.gov/cgi-bin/text-idx?node=13%3A1.0.1.1.19>).

### **Subcontract**

Any agreement, other than one involving an employer/employee relationship, entered into by an awardee of a funding agreement calling for supplies or services required solely for the performance of the original funding agreement.

### **United States**

The 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

### **Woman-Owned Small Business Concern (WOSB)**

An SBC that is at least 51% owned by one or more women, or in the case of any publicly owned business, at least 51% of the stock is owned by women, and women control the management and daily business operations.

### **Statutory Authority**

The Small Business Innovation Development Act of 1982, Pub. L. 97-219, as amended (15 U.S.C. 631 and 638), and title II of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760 et seq.).

## **II. Award Information**

Funding Instrument Type:                   Grant

Estimated Total Funding:	\$750,000
Expected Number of Awards:	10
Award Ceiling:	\$75,000 Per Budget Period
Award Floor:	\$75,000 Per Budget Period
Average Projected Award Amount:	\$75,000 Per Budget Period
Other	
6 month project and budget period	

### III. Eligibility Information

#### 1. Eligible Applicants

Each organization submitting an application **must** qualify as a **small business concern** as defined by the Small Business Administration **at the time of the award**.

In addition, the **primary employment of the principal investigator must** be with the small business firm at the time of award and during the conduct of the proposed research. That is, more than one-half of the principal investigator's working time must be spent with the small business firm during the period of performance. Also, for both Phase I and Phase II the research or R&D work **must** be performed in the United States. "United States" means the 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

**Joint ventures** are permitted, provided that the business entity created qualifies as a small business in accordance with the Small Business Act, 15 U.S.C. 631. For **Phase I**, the proposing firm must perform at least two-thirds of the research and/or analytic effort. Furthermore, the total of all consultant fees, facility leases or usage fees, and other subcontracts or purchase agreements may not exceed onethird of the total funding agreement price.

#### SBIR Eligibility Checklist

- For-profit small business concern.
- At least 51% U.S.-owned and independently operated.
- Small business located in the U.S.
- Principal investigator's primary employment with small business during the project.
- 500 or fewer employees.

#### **Additional Eligibility Considerations:**

##### Phase I to Phase II Transition Rate Benchmark

In accordance with guidance from the SBA, the HHS SBIR/STTR Program is implementing the Phase I to Phase II Transition Rate benchmark required by the SBIR/STTR Reauthorization Act of 2011. This Transition Rate requirement applies to SBIR and STTR Phase I applicants that have received more than 20 Phase I awards the past five fiscal years, excluding the most recently-awarded fiscal year. For these companies, the benchmark establishes a minimum number of Phase II awards the company must have received for a given number of Phase I awards received during the five-year period in order to be eligible to receive a new Phase I award. This requirement does not apply to companies that have received 20 or fewer Phase I awards over the five-year period.

Companies that apply for a Phase I award and do not meet or exceed the benchmark rate will not be eligible for a Phase I award for a period of one year from the date of the application submission. The Transition Rate is calculated as the total number of SBIR and STTR Phase II awards a company received during the past 5 fiscal years divided by the total number of SBIR and STTR Phase I awards it received during the past 5

fiscal years excluding the most recently-completed year. The benchmark minimum Transition Rate is 0.25. SBA calculates individual company Phase I to Phase II Transition Rates daily using SBIR and STTR award information across all federal agencies. For those companies that have received more than 20 Phase I awards over the past 5 years, SBA posts the company transition rates on the Company Registry at SBIR.gov. Information on the Phase I to Phase II Transition Rate requirement is available at SBIR.gov.

Applicants to this FOA that may have received more than 20 Phase I awards across all federal SBIR/STTR agencies over the past five (5) years should, prior to application preparation, verify that their company's Transition Rate on the Company Registry at SBIR.gov meets or exceeds the minimum benchmark rate of 0.25.

#### Phase II to Phase III Commercialization Benchmark

In accordance with guidance from the SBA, HHS, including NIH, SBIR/STTR Programs are implementing the Phase II to Phase III Commercialization Rate benchmark for Phase I applicants, as required by the SBIR/STTR Reauthorization Act of 2011. The Commercialization Rate Benchmark was published in a Federal Register notice on August 8, 2013 ([78 FR 48537](#)).

This requirement applies to companies that have received more than 15 Phase II awards from all agencies over the past 10 years, excluding the two most recently-completed Fiscal Years. Companies that meet this criterion must show an average of at least \$100,000 in revenues and/or investments per Phase II award or at least 0.15 (15%) patents per Phase II award resulting from these awards. This requirement does not apply to companies that have received 15 or fewer Phase II awards over the 10 year period, excluding the two most recently-completed Fiscal Years.

Information on the Phase II to Phase III Commercialization Benchmark is available at SBIR.gov.

Applicants to this FOA that may have received more than 15 Phase II awards across all federal SBIR/STTR agencies over the past ten (10) years should, prior to application preparation, verify that their company's Commercialization Benchmark on the Company Registry at SBIR.gov meets or exceeds the benchmark rate listed above.

Applicants that fail this benchmark will be notified by SBA annually and will not be eligible to receive New Phase I, Fast-track or Direct Phase II awards for a period of one year.

Administration for Community Living staff will examine all SBIR grant applications with the above considerations in mind. If it appears that an applicant organization does not meet the eligibility requirements, we will request an evaluation by the SBA. Under circumstances in which eligibility is unclear, we will not make an SBIR award until the SBA provides a determination.

Entities that are, at the time of award, small business concerns as defined by the Small Business Administration (SBA). This definition is included in the application package.

If it appears that an applicant organization does not meet the eligibility requirements, we will request an evaluation by the SBA. Under circumstances in which eligibility is unclear, we will not make an SBIR award until the SBA makes a determination that the applicant is eligible under its definition of small business concern.

#### Similar Proposals or Awards

WARNING -While it is permissible with proposal notification to submit identical proposals or proposals containing a significant amount of essentially equivalent work for consideration under numerous Federal program solicitations, it is unlawful to enter into funding agreements requiring essentially equivalent work. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award. If an applicant elects to submit identical proposals or proposals containing a significant amount of essentially equivalent work under other Federal program solicitations, a statement must be included in each such proposal indicating:

1. The name and address of the agencies to which proposals were submitted or from which awards were received.
2. Date of proposal submission or date of award.
3. Title, number, and date of solicitations under which proposals were submitted or awards received.
4. The specific applicable research topics for each proposal submitted or award received.
5. Titles of research projects.
6. Name and title of principal investigator or project manager for each proposal submitted or award received.

## Prior SBIR II Awards

If your small business has received more than 15 Phase II awards in the prior 5 fiscal years, the SBC must submit in its Phase I proposal: name of the awarding agency; date of award; funding agreement number; amount of award; topic or subtopic title; follow-on agreement amount; source and date of commitment; and current commercialization status for each Phase **II award**. **(This required proposal information will not be counted toward the proposal page limitation.)**

## **2. Cost Sharing or Matching**

Cost Sharing / Matching Requirement: No

## **3. Responsiveness and Screening Criteria**

### **Application Responsiveness Criteria**

Applicants must propose research and development projects that support NIDILRR's mission of improving lives of individuals with disabilities in at least one of the following outcome domains: (1) community living and participation, (2) health and function, or (3) employment.

### **Application Screening Criteria**

We will screen all applications and will reject any applications that:

- Are submitted after the deadline;
- Have narrative sections that are uploaded into grants.gov in formats other than PDF (PortableDocument) read-only, non-modifiable format, or in documents that are password protected;
- Propose a budget that exceeds \$75,000;
- Propose a project period that exceeds six months;
- Have a project narrative section that exceeds 50 pages.

The Project Narrative section of the application must be double-spaced, on 8 1/2" X 11" pages with 1" margins on both sides, and a standard font size of not less than 11. The project narrative must not exceed 50 double-spaced pages. For project narratives that exceed 50 double-spaced pages, NIDILRR will instruct reviewers to disregard all of the content on the pages beyond the 50th page.

## **IV. Application and Submission Information**

### **1. Address to Request Application Package**

Application materials can be obtained from <http://www.grants.gov> or [http://www.acf.hhs.gov/Funding\\_Opportunities/Announcements/Index.aspx](http://www.acf.hhs.gov/Funding_Opportunities/Announcements/Index.aspx).

Please note, ACL is requiring applications for all announcements to be submitted electronically through <http://www.grants.gov>. The Grants.gov (<http://www.grants.gov>) registration process can take several days. If your organization is not currently registered with <http://www.grants.gov>, please begin this process

immediately. For assistance with <http://www.grants.gov>, please contact them at [support@grants.gov](mailto:support@grants.gov) or 1-800-518-4726 between 7 a.m. and 9 p.m. Eastern Time.

- At the <http://www.grants.gov> website, you will find information about submitting an application electronically through the site, including the hours of operation. ACL strongly recommends that you do not wait until the application due date to begin the application process through <http://www.grants.gov> because of the time involved to complete the registration process.
- All applicants must have a DUNS number (<http://fedgov.dnb.com/webform/>) and be registered with the System for Award Management (SAM, [www.sam.gov](http://www.sam.gov)) and maintain an active SAM registration until the application process is complete, and should a grant be made, throughout the life of the award. Applicants should finalize a new, or renew an existing, registration at least two weeks before the application deadline. This action should allow you time to resolve any issues that may arise. Failure to comply with these requirements may result in your inability to submit your application or receive an award. Maintain documentation (with dates) of your efforts to register or renew at least two weeks before the deadline. See the SAM Quick Guide for Grantees at: [https://www.sam.gov/sam/transcript/SAM\\_Quick\\_Guide\\_Grants\\_Registrations-v1.6.;pdf](https://www.sam.gov/sam/transcript/SAM_Quick_Guide_Grants_Registrations-v1.6.;pdf).
- The agency is prohibited from making an award until an applicant has complied with these requirements. At the time an award is ready to be made, if the intended recipient has not complied with these requirements, the agency:
  - May determine that the applicant is not qualified to receive an award; and
  - May use that determination as a basis for making an award to another applicant.

Note: Once your SAM registration is active, you will need to allow 24 to 48 hours for the information to be available in Grants.gov before you can submit an application through Grants.gov. This action should allow you time to resolve any issues that may arise. Failure to comply with these requirements may result in your inability to submit your application or receive an award.

- **Note:** Failure to submit the correct suffix can lead to delays in identifying your organization and access to funding in the Payment Management System.
- Effective October 1, 2010, HHS requires all entities that plan to apply for and ultimately receive Federal grant funds from any HHS Operating/Staff Division (OPDIV/STAFFDIV) **or receive subawards directly from the recipients of those grant funds** to be:
  1. Be registered in SAM prior to submitting an application or plan;
  2. Maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by an OPDIV; and
  3. Provide its DUNS number in each application or plan to submit to the OPDIV.

Additionally, all first-tier subaward recipients must have a DUNS number at the time the subaward is made.

- Since October 1, 2003, The Office of Management and Budget has required applicants to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. It is entered on the SF 424. It is a unique, **nine-digit identification number**, which provides unique identifiers of single business entities. The DUNS number is *free and easy* to obtain.
- Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 1-866-705-5711 or by using this link to access a guide: [http://www.whitehouse.gov/sites/default/files/omb/grants/duns\\_num\\_guide.pdf](http://www.whitehouse.gov/sites/default/files/omb/grants/duns_num_guide.pdf).
- You must submit all documents electronically, including all information included on the SF424 and all necessary assurances and certifications.
- **Your application must comply with any page limitation requirements described in this Program Announcement.**
- After you electronically submit your application, you will receive an automatic acknowledgement

from <http://www.grants.gov> that contains <http://www.grants.gov> tracking number. The Administration for Community Living will retrieve your application form from <http://www.grants.gov>.

U.S. Department of Health and Human Services  
Administration for Community Living  
Patricia Barrett  
NIDILRR  
Phone Number: (202) 795-7303  
E-mail: [patricia.barrett@acl.hhs.gov](mailto:patricia.barrett@acl.hhs.gov)

## 2. Content and Form of Application Submission

### Letter of Intent

#### Letter of Intent

Due Date for Letter of Intent: **03/30/2016**

Notice of Intent to Apply: Due to the open nature of the SBIR priorities announced here and to assist with the selection of reviewers for this competition, NIDILRR is requesting all potential applicants submit a letter of intent (LOI). The submission is not mandatory and the content of the LOI will not be peer reviewed or otherwise used to rate an application.

Each LOI should be limited to a maximum of four pages and include the following information:

- (1) the title of the proposed project, the name of the applicant, the name of the Project, Director or Principal Investigator (PI), and the names of partner institutions and entities;
- (2) a brief statement of the vision, goals, and objectives of the proposed project and a description of its proposed activities at a sufficient level of detail to allow NIDILRR to select potential peer reviewers;
- (3) a list of proposed project staff including the Project Director or PI and key personnel;
- (4) a list of individuals whose selection as a peer reviewer might constitute a conflict of interest due to involvement in proposal development, selection as an advisory board member, co-PI relationships, etc.; and
- (5) contact information for the Project Director or PI. Submission of a LOI is not a prerequisite for eligibility to submit an application.

NIDILRR will accept the optional LOI via mail (through the U.S. Postal Service or commercial carrier) or email, by [INSERT DATE 35 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The LOI must be sent to: Brian Bard, National Institute on Disability, Independent Living, and Rehabilitation Research, administration for Community Living, U.S. Department of Health and Human Services, 330 C Street, SW, Room 2510-B, Washington, DC 20201, Phone: 202-795-7298, email: [brian.bard@acl.hhs.gov](mailto:brian.bard@acl.hhs.gov)

For further information regarding the LOI submission process, contact Brian Bard, National Institute on Disability, Independent Living, and Rehabilitation Research, Administration for Community Living, U.S. Department of Health and Human Services, 330 C Street, SW, Room 2510-B, Washington, DC 20201, Phone: 202-795-7298, email: [brian.bard@acl.hhs.gov](mailto:brian.bard@acl.hhs.gov)

### Project Narrative

The project narrative portion of your application is where you describe your proposed project and address the general requirements for SBIR and the review criteria. This section should include a description of the project's goal(s) and major objectives.

Each applicant must limit the project narrative to the equivalent of no more than 50 pages, using the following standards:

- A page is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative. You are not required to double space titles, headings, footnotes, references, and captions, or text in charts, tables, figures, and graphs. Use a font that is not less than size 11.
- Use one of the following fonts: Times New Roman, Courier, Courier New or Arial.
- Include all critical information in the project narrative, minimizing the need for additional appendices.
- Ensure that you attach **.PDF files only** for any attachments to your application. PDF files are the only Grants.gov approved file type. Applicants must submit individual .PDF files only when attaching files to their application. Any attachments uploaded that are not .PDF files or that are password protected files will not be read.

**NOTE:** The page limit does not apply to the Application for Federal Assistance (SF 424), the table of contents, the budget narrative, the forms, the one page abstract, the resumes / vitae, the bibliography, or the letters of commitment / collaboration. However, the recommended page limit does apply to all of the project narrative section.

For project narratives that exceed 50 double-spaced pages, NIDILRR will instruct reviewers to disregard all of the content on the pages beyond the 50th page.

**Each applicant must limit their project narrative to the equivalent of no more than 50, double-spaced pages.**

**Be sure to:**

- Begin numbering the first page in Arabic numerals ("1") and number the pages consecutively throughout the document.
- Include all critical information in the project narrative, minimizing the need for additional appendices.
- Include a complete bibliography listing all material that was referenced in the project narrative (this does not count toward the page limit).

**Project Narrative Components**

1. Identification and Significance of the Problem or Opportunity

Make a clear statement of the specific technical problem or opportunity addressed and explain its importance.

2. Phase I Technical Objectives

State the specific objectives of the Phase I research and development effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

3. Phase I Work Plan

Include a detailed description of the Phase I R/R&D plan. The plan should indicate what will be done, where it will be done, and how the R/R&D will be carried out. The methods planned to achieve each objective or task should be discussed in detail.

4. Related R/R&D

Describe significant R/R&D that is directly related to the proposal including any conducted by the project manager/principal investigator or by the proposing SBC. Describe how it relates to the proposed effort, and any planned coordination with outside sources. The applicant must persuade reviewers of his or her

awareness of key, recent R/R&D conducted by others in the specific topic area.

#### **5. Key Individuals and Bibliography of Directly Related Work**

Identify key individuals involved in Phase I including their directly-related education, experience, and bibliographic information. Where vitae are extensive, summaries that focus on the most relevant experience or publications are desired and may be necessary to meet proposal size limitation.

#### **6. Relationship with Future R/R&D**

- State the anticipated results of the proposed approach if the project is successful (Phase I and II).
- Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort.

#### **7. Facilities**

Provide a detailed description, availability, accessibility and location of instrumentation and physical facilities proposed for Phase I.

#### **8. Consultants**

Describe any involvement of consultants in the planning and research stages of the project.

#### **9. Potential Post Applications**

Briefly describe:

- Whether and by what means the proposed project appears to have potential commercial application.
- Whether and by what means the proposed project appears to have potential use by the Federal Government (if, in fact, it does).

**The following application components are not considered part of the Project Narrative section, and do not count against an applicant's 50-page limit for the project narrative**

#### **Abstract**

The one-page abstract should be comprehensive description of what the whole (all years) project is, not a description of the competency of the institution or project director. It is not an executive summary.

Applicants are required to include a one-page (single- or double-spaced) project summary of the proposed R/R&D including at least the following:

1. Name and address of SBC.
2. Name and title of principal investigator or project manager.
3. Agency name, CFDA number (93.433), and the words "SBIR Phase I"
4. Title of project.
5. Technical abstract limited to two hundred words.
6. Summary of the anticipated results and implications of the approach (both Phases I and II) and the potential commercial applications of the research.

**Note: Nothing in this section should be proprietary or confidential.**

#### **Table of Contents**

The table of contents shows where and how the important sections of your proposal are organized. While the application will be submitted electronically, the reviewers may use printed copies during the review process. The table of contents will assist reviewers in more efficiently and effectively evaluating your application.

#### **Budget Narrative/Justification**

This part requires an itemized budget breakdown for the six-month project period and the basis for estimating the costs of personnel salaries, benefits, project staff travel, materials and supplies, consultants and subcontracts, indirect costs, and any other projected expenditures.

There are not additional cost share requirements for this program.

The Appendix section of this Funding Opportunity Announcement includes a sample format for your budget narrative/justification.

The application must include the submission of cost or budget data. Use the Standard Form 424A to present a complete budget summary for the proposed project dates. You must also provide a justification for this budget by including a detailed narrative description for each budget line item. This narrative will be uploaded separately from Standard Form 424A.

**Indirect Costs:** If your organization does not currently have a negotiated indirect cost rate and is applying for a grant, you may estimate the indirect cost rate using the most recent financial data such as audited financial statements or other financial reports. The indirect cost estimate, based on that information, should be included in your grant application. If the grant award is made and the U.S. Department of Health and Human Services provides the majority of federal funding to your organization, an indirect cost proposal (including supporting documentation) must be submitted to HHS within 90 days of award. More information on what you should know about indirect cost rates can be found at: <http://www.psc.gov/search/search-results.php?q=indirect+cost&;search=1>

After receipt of the proposal, the office will begin the process of negotiating and approving a provisional indirect cost rate for your organization. Under our current regulations, **a temporary indirect cost rate of 10% of direct salaries and wages** may be allowed until an indirect cost rate has been approved.

### Letters of Commitment / Collaboration

Include confirmation of the commitments to the project (should it be funded) made by key collaborating organizations and agencies in this part of the application. Any organization that is specifically named to have a significant role in carrying out the project should be considered an essential collaborator. Signed letters of commitment should be scanned and included as attachments in your application submitted to grants.gov.

### Resumes / Vitae

Resumes or vitae of staff or consultants should include information that is specifically pertinent to this proposed project.

### 3. Submission Dates and Times

Due Date for Applications: **04/25/2016**

Date for Informational Conference Call: 03/16/2016

Pre-Application Meeting: A pre-application teleconference meeting will be held between 1:00 p.m. and 3:00 p.m. on the date listed above for the informational conference call. Interested parties are invited to participate in the pre-application meeting to discuss the funding priority and to receive information and technical assistance. You must contact [Carolyn.Baron@acl.hhs.gov](mailto:Carolyn.Baron@acl.hhs.gov) by March 14, 2016 in order to participate in this meeting. NIDILRR staff also will be available to provide information and technical assistance via individual phone consultations from 3:30 p.m. to 4:30 p.m. on March 15, 2016. Requests for individual consultations during this one hour window must be made in advance to Carolyn Baron.

**Applications must be submitted electronically by 11:59 p.m. Eastern Time on the date listed immediately above for "Due Date for Applications."**

Applications that fail to meet the application due date will not be reviewed and will receive no further

consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with <http://www.grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful submission.

When you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: <http://www.grants.gov/web/grants/register.html>.

After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only.)

If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline because of technical problems with the Grants.gov system, please contact the person listed under For Further Information Contact in section VII of this notice and provide a written explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. ACL will contact you after a determination is made on whether your application will be accepted.

**Note: We will not consider your application for further review if you failed to fully register to submit your application to Grants.gov before the application deadline or if the technical problem you experienced is unrelated to the Grants.gov system.**

Unsuccessful submissions will require authenticated verification from <http://www.grants.gov> indicating system problems existed at the time of your submission. You will be required to provide an <http://www.grants.gov> submission error notification and/or tracking number in order to substantiate missing the application deadline due to systematic grants.gov problems.

Grants.gov (<http://www.grants.gov>) will automatically send applicants a tracking number and date of receipt verification once the application has been successfully received and validated in <http://www.grants.gov>.

#### 4. Intergovernmental Review

This funding opportunity announcement is not subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

#### 5. Funding Restrictions

**Note:** A recent Government Accountability Office (GAO) report has raised considerable concerns about grantees and contractors charging the Federal government for additional meals outside of the standard allowance for travel subsistence known as per diem expenses. Executive Orders on Promoting Efficient Spending (EO 13589) and Delivering Efficient, Effective and Accountable Government (EO 13576) have been issued and instruct Federal agencies to promote efficient spending. Therefore, if meals are to be charged in your proposal, applicants should understand such costs must meet the following criteria outlined in the Executive Orders and HHS Grants Policy Statement:

- Meals are generally unallowable except for the following:
  - For subjects and patients under study (usually a research program);
  - Where specifically approved as part of the project or program activity, e.g., in programs providing children's services (e.g., Headstart);

- When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement;
- As part of a per diem or subsistence allowance provided in conjunction with allowable travel; and
- Under a conference grant, when meals are a necessary and integral part of a conference, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. (Note: conference grant means the sole purpose of the award is to hold a conference)

## 6. Other Submission Requirements

### Protection of Human Subjects

Research activities involving human subjects by awards under these programs are subject to Regulations for the Protection of Human Subjects. You do not need an assurance or IRB approval as a condition of applying for this competition.

If you marked "Yes" for Item 3 on the Supplemental Information for SF 424, you must provide a human subjects "exempt research" or "nonexempt research" narrative. Insert the narrative(s) in the space provided. If you have multiple projects and need to provide more than one narrative, please indicate which project each set of responses addresses.

A. Exempt Research Narrative. If you marked "Yes" for item 3a. and designated exemption number(s), provide the "exempt research" narrative. The narrative must contain sufficient information about the involvement of human subjects in the proposed research to allow a determination that the designated exemption(s) are appropriate. The narrative must be succinct. In addition, narratives are required for each participating partner if research is being conducted at other sites.

B. Nonexempt Research Narrative. If you marked "No" for item 3a., you must provide the "nonexempt research" narrative. The narrative must address the seven points. Although no specific page limitation applies to this section of the application, be succinct.

Human Subject Requirements for HHS grants. If your proposed project(s) involves research on human subjects, you must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects, unless that research is exempt as specified in the regulation. All awardees and their performance sites engaged in research involving human subjects must have or obtain:

(1) an assurance of compliance with the Regulations, and (2) initial and continuing approval of the research by an appropriately constituted and registered institutional review board. In order to obtain a Federal wide Assurance (FWA) of Protection for Human Subjects, the applicant may complete an on-line application at the Office for Human Research Protections (OHRP) website or write to the OHRP for an application. To obtain a FWA, contact OHRP at: <http://www.hhs.gov/ohrp>.

### Certifications and Statements

**The applicant must respond to the following certifications and statements as required by the Small Business Administration. Please go to the "Related Documents" tab in grants.gov to download a blank certification form. The completed certification form must then be uploaded to the application in Grants.gov under the section for "Attachments".**

**The following is provided for reference, please complete the information on the form you download from the "Related Documents" tab in Grants.gov**

**Certification for Applicants that are Majority-Owned by Multiple Venture Capital Operating Companies, Hedge Fund or Private Equity Firms**

Any small businesses that is majority-owned by multiple venture operating companies (VCOCs), hedge funds or private equity firms and are submitting an application for and SBIR funding agreement must complete this certification prior to submitting an application. This includes checking all of the boxes and having an authorized officer of the applicant sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on the information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award and meets the specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the funding agreement officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the funding agreement officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

(1) The applicant is NOT more than 50% owned by a single VCOC, hedge fund or private equity firm.

Yes                  No

(2) The applicant is more than 50% owned by multiple domestic business concerns that are VCOCs, hedge funds, or private equity firms.

Yes                  No

(3) I have registered with SBA at [www.SBIR.gov](http://www.SBIR.gov) as a business that is majority-owned by multiple VCOCs, hedge funds or private equity firms.

Yes                  No

I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

All the statements and information provided in this form and any documents submitted are true, accurate and complete. If assistance was obtained in completing this form and the supporting documentation, I have personally reviewed the information and it is true and accurate. I understand that, in general, these statements are made for the purpose of determining eligibility for an SBIR funding agreement and continuing eligibility.

I understand that the certifications in this document are continuing in nature. Each SBIR funding agreement for which the small business submits an offer or application or receives an award constitutes a restatement and reaffirmation of these certifications.

I understand that I may not misrepresent status as small business to: 1) obtain a contract under the Small Business Act; or 2) obtain any benefit under a provision of Federal law that references the SBIR Program.

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the SBIR applicant or awardee, that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. §1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. §3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Signature:	Date:
Print Name (First, Middle, Last)	
Title:	
Business Name:	

### **Small Business Certification**

Does the offeror certify that it is a small business concern and meets the definition as stated in the program solicitation or that it will meet that definition at the time of award?

Yes                  No

**Number of Employees including all affiliates (average for preceding 12 months):** \_\_\_\_\_

### **Socially and Economically Disadvantaged SBC Certification**

Does the offeror qualify as a socially and economically disadvantaged SBC and meet the definition as stated in this program solicitation?

Yes                  No

### **Woman-owned SBC Certification**

Does the offeror qualify as a woman-owned SBC and meet the definition as stated in this program solicitation?

Yes                  No

### **HUBZone-owned SBC Certification**

Does the offeror qualify as a HUBZone-owned SBC and meet the definition as stated in this solicitation?

Yes                  No                  *The website listed below contains information about the SBA's HUBZone program:* <http://www.sba.gov/hubzone/>

### **Historical Black College or University or Minority Institution (HBCU/MI) Certification**

Is a Historically Black College or University or Minority Institution (HBCU/MI) participating in this effort as a subcontractor?

Yes                  No

If yes, please provide the name of the entity proposed: \_\_\_\_\_

### **Primary Employment Certification**

Is the primary employment (51 percent or more time) of the principal investigator with the proposing firm?

Yes      No

### **Corporate Entity Certification**

Is more than 50 percent of the firm owned or managed by a corporate entity?

Yes      No

### **Manufacturing-Related Project Certification**

If R/R&D from an eventual Phase II award leads to a completed product is it possible that this product will be manufactured (e.g. production) on a wide scale basis?

Yes      No

*In cases where there is a tie in the award selection process, ED will give priority to projects that are manufacturing-related. (This "tie-breaker" specification allows the ED program to apply an additional preference without compromising the quality standards or established criteria of the program.)*

### **Required Certification to Submit with Interim and Final Reports**

Submission of this certification is required with the all interim reports and the final report:

- I certify that the Principal Investigator currently is \_\_\_\_\_, is not \_\_\_\_\_ "primarily employed" by the firm as defined in the SBIR solicitation.
- I certify that the work under this project has \_\_\_\_\_, has not \_\_\_\_\_, been submitted for funding to another Federal agency and that it has \_\_\_\_\_, has not \_\_\_\_\_ been funded under any other Federal grant, contract, or subcontract.
- I certify that to the best of my knowledge the work for which payment is hereby requested was performed in accordance with the award terms and conditions and that payment is due and has not been previously requested.
- I certify that to the best of my knowledge, (1) the statements herein (excluding scientific hypotheses and scientific opinions) are true and complete; and (2) the text and graphics in this report as well as any accompanying publications or other documents, unless otherwise indicated, are the original work of the signatories or individuals working under their supervision.
- I understand that the willful provision of false information or concealing a material fact in this report or any other communication submitted to ED is a criminal offense (U.S. Code, title 18, Section 1001).

Authorized Company Officer:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Principal Investigator:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## **Statements**

The applicant must respond to the following statements required by the Small Business Administration.

### **Duplicate Research Statement**

The applicant and/or principal investigator (*choose one: has or has not*) submitted proposals for essentially equivalent work under other Federal program solicitations.

The applicant and/or principal investigator (*choose one: has or has not*) received other Federal awards for essentially equivalent work. (For more information regarding how to identify proposals and/or awards, see [Section \(III\)\(E\)\(10\), Technical Content \(Project Narrative\), Similar Proposals or Awards](#)).

### **Disclosure Permission Statement**

Will the applicant permit the Government to disclose the title and technical abstract page of the proposed project, plus the name, address, and telephone number of the corporate official of the applicant's firm, if the proposal does not result in an award, to concerns that may be interested in contacting you for further information?

**Yes                  No**

For further information, please contact:

Patricia Barrett  
NIDILRR  
330 C Street, SW  
Washington, DC 22201

## **V. Application Review Information**

### **1. Criteria**

All Phase I proposals will be evaluated and judged on a competitive basis. NIDILRR uses external peer reviewers to evaluate applications. Reviewers score each application by assigning a maximum of 100 points across the following criteria:

**IMPORTANCE OF THE PROBLEM** | Maximum Points:20

In determining the importance of the problem, the Director considers the following factors:

- (i) The extent to which the applicant clearly describes the need and target population.
- (ii) The extent to which the proposed activities address a significant need of one or more disabled populations.
- (iii) The extent to which the proposed project will have beneficial impact on the target population.

**DESIGN OF DEVELOPMENT ACTIVITIES** | Maximum Points:25

In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers the following factors:

- (i) The extent to which the plan for development, clinical testing, and evaluation of new devices and technology is likely to yield significant products or techniques, including consideration of the extent to which—
  - (A) The proposed project will use the most effective and appropriate technology available in developing the new device or technique;

- (B) The proposed development is based on a sound conceptual model that demonstrates an awareness of the state-of-the-art in technology;
- (C) The new device or technique is likely to be cost-effective and useful;
- (D) The new device or technique has the potential for commercial or private manufacture, marketing, and distribution of the product.

<b>DESIGN OF RESEARCH ACTIVITIES</b>	<b>Maximum Points:25</b>
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In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers the following factors:

- (i) The extent to which the methodology of each proposed research activity is meritorious, including consideration of the extent to which-
  - (A) The proposed design includes a comprehensive and informed review of the current literature, demonstrating knowledge of the state-of-the-art;
  - (B) Each research hypothesis is theoretically sound and based on current knowledge;
  - (C) Each sample population is appropriate and of sufficient size;
  - (D) The data collection and measurement techniques are appropriate and likely to be effective; and
  - (E) The data analysis methods are appropriate.

<b>PROJECT STAFF</b>	<b>Maximum Points:15</b>
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In determining the quality of the project staff, the Director considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

In addition, the Director considers the following:

- (i) The extent to which the key personnel and other key staff have appropriate training and experience in disciplines required to conduct all proposed activities.
- (ii) The extent to which the commitment of staff time is adequate to accomplish all the proposed activities of the project.

<b>ADEQUACY AND REASONABLENESS OF THE BUDGET</b>	<b>Maximum Points:5</b>
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In determining the adequacy and the reasonableness of the proposed budget, the Director considers the following factors:

- (i) The extent to which the costs are reasonable in relation to the proposed project activities.
- (ii) The extent to which the budget for the project, including any subcontracts, is adequately justified to support the proposed project activities.

<b>ADEQUACY AND ACCESSIBILITY OF RESOURCES</b>	<b>Maximum Points:10</b>
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In determining the adequacy and accessibility of resources, the Director considers the following factors:

- (i) The extent to which the applicant is committed to provide adequate facilities, equipment, other resources, including administrative support, and laboratories, if appropriate.

## 2. Review and Selection Process

As required by 2 CFR 200 of the Uniform Guidance, effective January 1, 2016, ACL is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS), <https://www.fapiis.gov> before making any award in excess of the simplified acquisition threshold (currently \$150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency has previously entered into FAPIIS. ACL will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 2 CFR § 200.205 Federal Awarding Agency Review of Risk Posed by Applicants ([http://www.ecfr.gov/cgi-bin/text-idx?node=se2.1.200\\_1205&rgn=div8](http://www.ecfr.gov/cgi-bin/text-idx?node=se2.1.200_1205&rgn=div8)).

Final award decisions will be made by the Administrator, ACL. In making these decisions, the Administrator's primary consideration will be the ranking of applications by the review panel. The Administrator may also consider the reasonableness of the estimated cost to the government considering the available funding and anticipated results and the likelihood that the proposed project will result in the benefits expected. Under 45 CFR part 75, Section 205, item (3) history of performance, is an item that is also reviewed. In addition, in making a competitive grant award, the Administrator of ACL also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Health and Human Services 45 CFR part 75.

### **3. Anticipated Announcement Award Date**

Successful applicants will receive an electronic Notice of Award no later than September 30, 2016. All applicants will receive feedback from the peer review process no later than September 30, 2016.

## **VI. Award Administration Information**

### **1. Award Notices**

If your application is successful, we send you a Notice of Award (NOA); or we may send you an email containing a link to access an electronic version of your NOA. If your application is not selected for funding or is not evaluated, we will notify you.

### **2. Administrative and National Policy Requirements**

The award is subject to DHHS Administrative Requirements, which can be found in 45CFR Part 75 and the Standard Terms and Conditions, included in the Notice of Award as well as implemented through the HHS Grants Policy Statement.

A standard term and condition of award will be included in the final notice of award; all applicants will be subject to a term and condition that applies to the terms of 48 CFR section 3.908 to the award, and requires the grantees inform their employee in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce.

### **Other Administrative and National Policy Requirements**

## **Release of Proposal Review Information**

After final award decisions have been announced, the technical evaluations of the applicant's proposal will be provided to the applicant. No one other than the Principal Investigator may receive the technical evaluations. Applicants normally receive their evaluations within six (6) to eight (8) weeks following the announcement of the awards. The identity of the reviewers will not be disclosed.

## **Innovations, Inventions and Patents**

### **1. Proprietary Information**

Information contained in unsuccessful proposals will remain the property of the applicant. The Government may, however, retain copies of all proposals. Public release of information in any proposal submitted will be subject to existing statutory and regulatory requirements. If proprietary information is provided by an applicant in a proposal, which constitutes a trade secret, proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law. This information must be clearly marked by the applicant with the term "confidential proprietary information" and the following legend must appear on the title page of the proposal:

*"These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages \_\_\_ of this proposal."*

Any other legend may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration, without assuming any liability for inadvertent disclosure. The Government will limit dissemination of such information to within official channels.

### **2. Rights in Data Developed Under SBIR Funding Agreements**

To preserve the SBIR data rights of the awardee, the legend (or statements) used in the SBIR Data Rights clause included in the SBIR award must be affixed to any submissions of technical data developed under that SBIR award. If no Data Rights clause is included in the SBIR award, the following legend, at a minimum, should be affixed to any data submissions under that award.

*"These SBIR data are furnished with SBIR rights under Funding Agreement No. \_\_\_ (and subcontract No. \_\_\_ if appropriate), Awardee Name \_\_\_, Address, Expiration Period of SBIR Data Rights \_\_\_. The Government may not use, modify, reproduce, release, perform, display, or disclose technical data or computer software marked with this legend for (choose four (4) or five (5) years). After expiration of the (4-or 5-year period), the Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties, except that any such data that is also protected and referenced under a subsequent SBIR award shall remain protected through the protection period of that subsequent SBIR award. Reproductions of these data or software must include this legend."*

### **3. Copyrights**

With prior written permission of the contracting officer, the awardee normally may copyright and publish (consistent with appropriate national security considerations, if any) material developed with HHS support. HHS receives a royalty-free license for the Federal Government and requires that each publication contain an appropriate acknowledgement and disclaimer statement.

### **4. Patents**

Small business concerns normally may retain the principal worldwide patent rights to any invention developed with Government support. In such circumstances, the Government receives a royalty-free license for Federal Government use, reserves the right to require the patent holder to license others in certain circumstances, and may require that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, the Government will not make public any information disclosing a Government-supported invention for a minimum 4-year period (that may be extended by subsequent SBIR funding agreements) to allow the awardee a reasonable time to pursue a patent.

#### 5. Invention Reporting

SBIR awardees must report inventions to the awarding agency within 2 months of the inventor's report to the awardee. The reporting of inventions may be accomplished by submitting paper documentation, including fax.

#### 6. Profit or Fee

The SBA has stated that SBIR funding agencies are to provide for a **reasonable** fee or profit on SBIR funding agreements, including grants, **consistent with normal profit margins provided to profit-making firms for R/R&D work** (SBIR Policy Directive). Questions pertaining to this area can be discussed with the NIDILRR personnel listed in Section VII of this funding opportunity announcement.

an applicant may request a profit or fee (hereafter, "fee"), in addition to direct and indirect costs, as part of its application. Fee amounts **shall not exceed 8 percent of total costs**, exclusive of fee. Funds requested for a profit/fee must be included in the funds specified as requested in Section A--Budget Summary of the application forms. The budget cannot exceed the maximum amount allowable in any budget year. Applications that exceed the maximum amount allowable in any year will not be reviewed.

#### 7. Joint Ventures or Limited Partnerships

Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern as defined in this program announcement.

#### 8. Research and Analytical Work – Subcontracting Limits

For **Phase I a minimum of two-thirds of the research and/or analytical effort** must be performed by the proposing small business concern unless otherwise approved in writing by the funding agreement officer after consultation with the agency SBIR Program Manager/Coordinator.

#### Additional Information

1. This program announcement is intended for informational purposes and reflects current planning. If there is an inconsistency between the information contained herein and the terms of any resulting SBIR funding agreement, then the terms of the funding agreement are controlling.
2. Before award of an SBIR funding agreement, the Government may request the applicant to submit certain organizational, management, personnel, and financial information to assure responsibility of the applicant.
3. The Government is not responsible for any monies expended by the applicant before award of any funding agreement.
4. This program solicitation is not an offer by the Government and does not obligate the Government to make any specific number of awards. Also, awards under the SBIR Program are contingent upon the availability of funds.
5. The SBIR program is not a substitute for existing unsolicited application mechanisms. The Government shall not accept unsolicited applications under the SBIR program in either Phase I or Phase II.
6. If an award is made pursuant to an application submitted under this program announcement, the grantee

will be required to certify that he or she has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government.

7. In the interests of those with special needs, the applicant is encouraged to develop products that include alternate formats (e.g., closed- or open-captioning for films and/or videotapes, Braille, large print, audiotape).

### **Scientific and Technical Information Sources**

Certain sources can provide information that can be useful in preparing SBIR applications. The Internet sites listed below can provide you with helpful material and links to other sites.

#### SBIR Program-Related Information is available:

Small Business Administration (SBA)

[www.sba.gov](http://www.sba.gov)

SBIR.gov (formerly Tech-Net)

[www.sbir.gov](http://www.sbir.gov)

#### Information about NIDILRR's currently-funded grants under this and other programs:

National Rehabilitation Information Center

[www.naric.com](http://www.naric.com)

### **3. Reporting**

If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 45 CFR part 75 should you receive funding under the competition. This does not apply if you have an exception under 45 CFR part 75.

At the end of your project period, you must submit a final performance report, including financial information, as required in your award's terms and conditions. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as required under 45 CFR part 75.

All NIDILRR grantees will submit their annual and final reports through NIDILRR's online reporting system and as designated in the terms and conditions of your NOA.

### **4. FFATA and FSRS Reporting**

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (<http://www.FSRS.gov>) for all sub-awards and sub-contracts issued for \$25,000 or more as well as addressing executive compensation for both grantee and sub-award organizations.

For further guidance please see the following link: [http://www.acl.gov/Funding\\_Opportunities/Grantee\\_Info/FFATA.aspx](http://www.acl.gov/Funding_Opportunities/Grantee_Info/FFATA.aspx)

## **VII. Agency Contacts**

### **Project Officer**

Brian Bard

[Brian.Bard@acl.hhs.gov](mailto:Brian.Bard@acl.hhs.gov)

### **Grants Management Specialist**

Patricia Barrett

[Patricia.Barrett@acl.hhs.gov](mailto:Patricia.Barrett@acl.hhs.gov)

202-795-7303

## VIII. Other Information

### 1. Application Elements

- a. SF 424, required – Application for Federal Assistance (See “Instructions for Completing Required Forms” for assistance).
- b. SF 424A, required – Budget Information. (See Attachment A for Instructions; See “Standard Form 424A – Sample Format” for an example of a completed SF 424A).
- c. Separate Budget Narrative/Justification, required (See “Budget Narrative/Justification - Sample Format” for examples and “Budget Narrative/Justification – Sample Template.”)

NOTE: Applicants requesting funding for multi-year grant projects are REQUIRED to provide a Narrative/Justification for each year of potential grant funding, as well as a combined multi-year detailed Budget Narrative/Justification.

- d. SF 424B – Assurance, required. Note: Be sure to complete this form according to instructions and have it signed and dated by the authorized representative (see item 18d on the SF 424).
- e. Lobbying Certification, required
- f. Proof of non-profit status, if applicable
- g. Copy of the applicant's most recent indirect cost agreement, if requesting indirect costs. If any sub-contractors or sub-grantees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.
- h. Project Narrative with Work Plan, required (See “Project Work Plan – Sample Template” for a formatting suggestions).
- i. Organizational Capability Statement and Vitae for Key Project Personnel.
- j. Letters of Commitment from Key Partners, if applicable.
- k. Abstract
- l. Supplemental Information Form for the SF-424

Note: NIDILRR does not require applicants to submit an organizational capability statement outside of their project narrative. NIDILRR assesses organizational capability via the peer review process, including application of criteria related to project staff, and the adequacy and accessibility of applicant resources.

## **2. The Paperwork Reduction Act of 1995 (P.L. 104-13)**

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The project description and Budget Narrative/Justification is approved under OMB control number 0985-0018 which expires on 3/12/17. Public reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection information.

## **Appendix**

### **Instructions for Completing Required Forms**

This section provides step-by-step instructions for completing the four (4) standard Federal forms required as part of your grant application, including special instructions for completing Standard Budget Forms 424 and 424A. Standard Forms 424 and 424A are used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. ACL does not require all the information on these Standard Forms. Accordingly, please use the instructions below in lieu of the standard instructions attached to SF 424 and 424A to complete these forms.

#### **a. Standard Form 424**

**1. Type of Submission:** (REQUIRED): Select one type of submission in accordance with agency instructions.

- Preapplication
- Application
- Changed/Corrected Application – If ACL requests, check if this submission is to change or correct a previously submitted application.

**2. Type of Application:** (REQUIRED) Select one type of application in accordance with agency instructions.

- New
- Continuation
- Revision

**3. Date Received:** Leave this field blank.

**4. Applicant Identifier:** Leave this field blank

**5a Federal Entity Identifier:** Leave this field blank

**5b. Federal Award Identifier:** For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned Federal award (grant) number.

**6. Date Received by State:** Leave this field blank.

**7. State Application Identifier:** Leave this field blank.

**8. Applicant Information:** Enter the following in accordance with agency instructions:

**a. Legal Name:** (REQUIRED): Enter the name that the organization has registered with the System for

Award Management (SAM), formally the Central Contractor Registry. Information on registering with SAM may be obtained by visiting the Grants.gov website (<http://www.grants.gov>) or by going directly to the SAM website ([www.sam.gov](http://www.sam.gov)).

**b. Employer/Taxpayer Number (EIN/TIN):** (REQUIRED) Enter the Employer or Taxpayer Identification Number (EIN or TIN) as assigned by the Internal Revenue Service. In addition, we encourage the organization to include the correct suffix used to identify your organization in order to properly align access to the Payment Management System.

**c. Organizational DUNS:** (REQUIRED) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet. Information on obtaining a DUNS number may be obtained by visiting the Grants.gov website (<http://www.grants.gov>). Your DUNS number can be verified at <http://fedgov.dnb.com/webform/>.

**d. Address:** (REQUIRED) Enter the complete address including the county.

**e. Organizational Unit:** Enter the name of the primary organizational unit (and department or division, if applicable) that will undertake the project.

**f. Name and contact information of person to be contacted on matters involving this application:** Enter the name (First and last name required), organizational affiliation (if affiliated with an organization other than the applicant organization), telephone number (Required), fax number, and email address (Required) of the person to contact on matters related to this application.

**9. Type of Applicant:** (REQUIRED) Select the applicant organization “type” from the following drop down list.

A. State Government B. County Government C. City or Township Government D. Special District Government E. Regional Organization F. U.S. Territory or Possession G. Independent School District H. Public/State Controlled Institution of Higher Education I. Indian/Native American Tribal Government (Federally Recognized) J. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribally Designated Organization L. Public/Indian Housing Authority M. Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education) N. Nonprofit without 501C3 IRS Status (Other than Institution of Higher Education) O. Private Institution of Higher Education P. Individual Q. For-Profit Organization (Other than Small Business) R. Small Business S. Hispanic-serving Institution T. Historically Black Colleges and Universities (HBCUs) U. Tribally Controlled Colleges and Universities (TCCUs) V. Alaska Native and Native Hawaiian Serving Institutions W. Non-domestic (non-US) Entity X. Other (specify)

**10. Name Of Federal Agency:** (REQUIRED) Enter U.S. Administration for Community Living

**11. Catalog Of Federal Domestic Assistance Number>Title:** The CFDA number can be found on page one of the Program Announcement.

**12. Funding Opportunity Number>Title:** (REQUIRED) The Funding Opportunity Number and title of the opportunity can be found on page one of the Program Announcement.

**13. Competition Identification Number>Title:** Leave this field blank.

**14. Areas Affected By Project:** List the largest political entity affected (cities, counties, state etc).

**15. Descriptive Title of Applicant's Project:** (REQUIRED) Enter a brief descriptive title of the project

(This is not a narrative description).

**16. Congressional Districts Of:** (REQUIRED) 16a. Enter the applicant's Congressional District, and 16b. Enter all district(s) affected by the program or project. Enter in the format: 2 characters State Abbreviation – 3 characters District Number, e.g., CA-005 for California 5th district, CA-012 for California 12<sup>th</sup> district, NC-103 for North Carolina's 103rd district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all. See the below website to find your congressional district:  
<http://www.house.gov/>

**17. Proposed Project Start and End Dates:** (REQUIRED) Enter the proposed start date and final end date of the project. **If you are applying for a multi-year grant, such as a 3 year grant project, the final project end date will be 3 years after the proposed start date.** In general, all start dates on the SF424 should be the 1<sup>st</sup> of the month and the end date of the last day of the month of the final year, for example 7/01/2014 to 6/30/2017. The Grants Officer can alter the start and end date at their discretion.

**18. Estimated Funding:** (REQUIRED) If requesting multi-year funding, enter the full amount requested from the Federal Government in line item 18.a., as a multi-year total. For example and illustrative purposes only, if year one is \$100,000, year two is \$100,000, and year three is \$100,000, then the full amount of Federal funds requested would be reflected as \$300,000. The amount of matching funds is denoted by lines b. through f. with a combined Federal and non-Federal total entered on line g. Lines b. through f. represents contributions to the project by the applicant and by your partners during the total project period, broken down by each type of contributor. The value of in-kind contributions should be included on appropriate lines, as applicable.

**NOTE:** Applicants should review cost sharing or matching principles contained in Subpart C of 45 CFR Part 75 before completing Item 18 and the Budget Information Sections A, B and C noted below.

All budget information entered under item 18 should cover the total project period. For sub-item 18a, enter the Federal funds being requested. Sub-items 18b-18e are considered matching funds. The dollar amounts entered in sub-items 18b-18f must total at least 1/3<sup>rd</sup> of the amount of Federal funds being requested (the amount in 18a). For a full explanation of ACL's match requirements, see the information in the box below. For sub-item 18f (program income), enter only the amount, if any, that is going to be used as part of the required match. Program Income submitted as match will become a part of the award match and recipients will be held accountable to meet their share of project expenses even if program income is not generated during the award period.

There are two types of match: 1) non-Federal cash and 2) non-Federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-grantees, contractors and consultants, are considered **matching funds**. Examples of **non-Federal cash match** includes budgetary funds provided from the applicant agency's budget for costs associated with the project. Generally, most contributions from sub-contractors or sub-grantees (third parties) will be non-Federal in-kind matching funds. Volunteered time and use of third party facilities to hold meetings or conduct project activities may be considered in-kind (third party) donations.

**NOTE: Indirect charges** may only be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency; or (2) the applicant is a state or local government agency. State governments should enter the amount of indirect costs determined in accordance with DHHS requirements. **If indirect costs are to be included in the application, a copy of the approved indirect cost agreement must be included with the application. Further, if any sub-contractors or sub-grantees are requesting indirect costs, a copy of the latest**

**approved indirect cost agreements must also be included with the application, or reference to an approved cost allocation plan.**

**19. Is Application Subject to Review by State Under Executive Order 12372 Process?** Please refer to IV. Application and Submission Information, 4. Intergovernmental Review to determine if the ACL program is subject to E.O. 12372 and respond accordingly.

**20. Is the Applicant Delinquent on any Federal Debt?** (Required) This question applies to the applicant organization, not the person who signs as the authorized representative. If yes, include an explanation on the continuation sheet.

**21. Authorized Representative:** (Required) To be signed and dated by the authorized representative of the applicant organization. Enter the name (First and last name required), title (Required), telephone number (Required), fax number, and email address (Required) of the person authorized to sign for the applicant. A copy of the governing body's authorization for you to sign this application as the official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

#### **Standard Form 424A**

NOTE: Standard Form 424A is designed to accommodate applications for multiple grant programs; thus, for purposes of this ACL program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a multi-year budget. See Attachment B.**Section A Budget Summary**

#### **Section A - Budget Summary**

**Line 5:** Leave columns (c) and (d) blank. Enter TOTAL Federal costs in column (e) and total nonFederal costs (including third party in-kind contributions and any program income to be used as part of the grantee match) in column (f). Enter the sum of columns (e) and (f) in column (g).

#### **Section B Budget Categories**

Column 1: Enter the breakdown of how you plan to use the Federal funds being requested by object class category (see instructions for each object class category in Attachment C).

Column 2: Enter the breakdown of how you plan to use the non-Federal share by object class category.

Column 5: Enter the total funds required for the project (sum of Columns 1 and 2) by object class category.

#### **Section C – Non Federal Resources**

Column A: Enter the federal grant program.

Column B: Enter in any non-federal resources that the applicant will contribute to the project.

Column C: Enter in any non-federal resources that the state will contribute to the project.

Column D: Enter in any non-federal resources that other sources will contribute to the project.

Column E: Enter the total non-federal resources for each program listed in column A.

## **Section D –Forecasted Cash Needs**

**Line 13:** Enter Federal forecasted cash needs broken down by quarter for the first year only.

**Line 14:** Enter Non-Federal forecasted cash needs broken down by quarter for the first year.

Line 15: Enter total forecasted cash needs broken down by quarter for the first year.

Note: This area is not meant to be one whereby an applicant merely divides the requested funding by four and inserts that amount in each quarter but an area where thought is given as to how your estimated expenses will be incurred during each quarter. For example, if you have initial startup costs in the first quarter of your award reflect that in quarter one or you do not expect to have contracts awarded and funded until quarter three, reflect those costs in that quarter.

## **Section E – Budget Estimates of Federal Funds Needed for Balance of the Project (i.e. subsequent years 2, 3, 4 or 5 as applicable).**

Column A: Enter the federal grant program

Column B (first): Enter the requested year two funding.

Column C (second): Enter the requested year three funding.

Column D (third): Enter the requested year four funding, if applicable.

Column E (forth): Enter the requested year five funding, if applicable.

## **Section F – Other Budget Information**

**Line 21:** Enter the total Indirect Charges

**Line 22:** Enter the total Direct charges (calculation of indirect rate and direct charges).

**Line 23:** Enter any pertinent remarks related to the budget.

### **Separate Budget Narrative/Justification Requirement**

**Applicants requesting funding for multi-year grant programs are REQUIRED to provide a combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential grant funding. A separate Budget Narrative/Justification is also REQUIRED for each potential year of grant funding requested.**

For your use in developing and presenting your Budget Narrative/Justification, a sample format with examples and a blank sample template have been included in these Attachments. In your Budget Narrative/Justification, you should include a breakdown of the budgetary costs for all of the object class categories noted in Section B, across three columns: Federal; non-Federal cash; and non-Federal in-kind. Cost breakdowns, or justifications, are required for any cost of \$1,000 or for the thresholds as established in the examples. The Budget Narratives/Justifications should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Non-Federal cash as well as, sub-contractor or sub-grantee (third party) in-kind contributions designated as match must be clearly identified and explained in the Budget Narrative/Justification. The full Budget Narrative/Justification should be included in the application immediately following the SF 424

forms.

Line 6a: **Personnel:** Enter total costs of salaries and wages of applicant/grantee staff. Do not include the costs of consultants, which should be included under 6h Other.

**In the Justification:** Identify the project director, if known. Specify the key staff, their titles, and time commitments in the budget justification.

Line 6b: **Fringe Benefits:** Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate.

**In the Justification:** If the total fringe benefit rate exceeds 35% of Personnel costs, provide a breakdown of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement, etc. A percentage of 35% or less does not require a break down but you must show the percentage charged for each full/part time employee.

Line 6c: **Travel:** Enter total costs of all travel (local and non-local) for staff on the project. NEW: Local travel is considered under this cost item not under Other. Local transportation (all travel which does not require per diem is considered local travel). Do not enter costs for consultant's travel - this should be included in line 6h.

**In the Justification:** Include the total number of trips, number of travelers, destinations, purpose (e.g., attend conference), length of stay, subsistence allowances (per diem), and transportation costs (including mileage rates).

Line 6d: **Equipment:** Enter the total costs of all equipment to be acquired by the project. For all grantees, "equipment" is nonexpendable tangible personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. If the item does not meet the \$5,000 threshold, include it in your budget under Supplies, line 6e.

**In the Justification:** Equipment to be purchased with federal funds must be justified as necessary for the conduct of the project. The equipment must be used for project-related functions. Further, the purchase of specific items of equipment should not be included in the submitted budget if those items of equipment, or a reasonable facsimile, are otherwise available to the applicant or its subgrantees.

Line 6e: **Supplies:** Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d.

**In the Justification:** . For any grant award that has supply costs in excess of 5% of total direct costs (Federal or Non-Federal), you must provide a detailed break down of the supply items (e.g., 6% of \$100,000 = \$6,000 – breakdown of supplies needed). If the 5% is applied against \$1 million total direct costs (5% x \$1,000,000 = \$50,000) a detailed breakdown of supplies is not needed. Please note: any supply costs of \$5,000 or less regardless of total direct costs does not require a detailed budget breakdown (e.g., 5% x \$100,000 = \$5,000 – no breakdown needed).

Line 6f: **Contractual:** Regardless of the dollar value of any contract, you must follow your established policies and procedures for procurements and meet the minimum standards established in the Code of Federal Regulations (CFR's) mentioned below. Enter the total costs of all contracts, including (1) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.). Note: The 33% provision has been removed and line item budget detail is not required as long as you meet the established procurement standards. Also include any awards to organizations for the provision of technical assistance. Do not include payments to individuals on this line. Please be advised: A subrecipient is

involved in financial assistance activities by receiving a sub-award and a subcontractor is involved in procurement activities by receiving a sub-contract. Through the recipient, a subrecipient performs work to accomplish the public purpose authorized by law. Generally speaking, a sub-contractor does not seek to accomplish a public benefit and does not perform substantive work on the project. It is merely a vendor providing goods or services to directly benefit the recipient, for example procuring landscaping or janitorial services. In either case, you are encouraged to clearly describe the type of work that will be accomplished and type of relationship with the lower tiered entity whether it be labeled as a subaward or subcontract.

**In the Justification:** Provide the following three items – 1) Attach a list of contractors indicating the name of the organization; 2) the purpose of the contract; and 3) the estimated dollar amount. If the name of the contractor and estimated costs are not available or have not been negotiated, indicate when this information will be available. The Federal government reserves the right to request the final executed contracts at any time. If an individual contractual item is over the small purchase threshold, currently set at \$100K in the CFR, you must certify that your procurement standards are in accordance with the policies and procedures as stated in 45 CFR Part 75 for states, in lieu of providing separate detailed budgets. This certification should be referenced in the justification and attached to the budget narrative.

Line 6g: **Construction:** Leave blank since construction is not an allowable costs for this program.

Line 6h: **Other:** Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (i.e. for project volunteers this is different from personnel fringe benefits), non-contractual fees and travel paid directly to individual consultants, postage, space and equipment rentals/lease, printing and publication, computer use, training and staff development costs (i.e. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then rest assured this is where it belongs.

Note: A recent Government Accountability Office (GAO) report number 11-43, has raised considerable concerns about grantees and contractors charging the Federal government for additional meals outside of the standard allowance for travel subsistence known as per diem expenses. If meals are to be charged towards the grant they must meet the following criteria outlined in the Grants Policy Statement:

- *Meals are generally unallowable except for the following:*
- *For subjects and patients under study(usually a research program);*
- *Where specifically approved as part of the project or program activity, e.g., in programs providing children's services (e.g., Headstart);*
- *When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement;*
- *As part of a per diem or subsistence allowance provided in conjunction with allowable travel; and*
- *Under a conference grant, when meals are a necessary and integral part of a conference, provided that meal costs are not duplicated in participants' per diem or subsistence allowances (Note: the sole purpose of the grant award is to hold a conference).*

**In the Justification:** Provide a reasonable explanation for items in this category. For example, individual consultants explain the nature of services provided and the relation to activities in the work plan or indicate where it is described in the work plan. Describe the types of activities for staff development costs.

Line 6i: **Total Direct Charges:** Show the totals of Lines 6a through 6h.

Line 6j: **Indirect Charges:** Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. **State governments should enter the amount of indirect costs determined in accordance with DHHS requirements.** An applicant that will charge indirect

costs to the grant must enclose a copy of the current rate agreement. Indirect Costs can only be claimed on Federal funds, more specifically, they are to only be claimed on the Federal share of your direct costs. Any unused portion of the grantee's eligible Indirect Cost amount that are not claimed on the Federal share of direct charges can be claimed as un-reimbursed indirect charges, and that portion can be used towards meeting the recipient match.

Line 6k: **Total:** Enter the total amounts of Lines 6i and 6j.

Line 7: **Program Income:** As appropriate, include the estimated amount of income, if any, you expect to be generated from this project that you wish to designate as match (equal to the amount shown for Item 15(f) on Form 424). **Note:** Any program income indicated at the bottom of Section B and for item 15(f) on the face sheet of Form 424 will be included as part of non-Federal match and will be subject to the rules for documenting completion of this pledge. If program income is expected, but is not needed to achieve matching funds, **do not** include that portion here or on Item 15(f) of the Form 424 face sheet. Any anticipated program income that will not be applied as grantee match should be described in the Level of Effort section of the Program Narrative.

#### **c. Standard Form 424B – Assurances (required)**

This form contains assurances required of applicants under the discretionary funds programs administered by the Administration for Community Living. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

#### **d. Certification Regarding Lobbying (required)**

This form contains certifications that are required of the applicant organization regarding lobbying. Please note that a duly authorized representative of the applicant organization must attest to the applicant's compliance with these certifications.

#### **Proof of Non-Profit Status (as applicable)**

Non-profit applicants must submit proof of non-profit status. Any of the following constitutes acceptable proof of such status:

- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

#### **Indirect Cost Agreement**

Applicants that have included indirect costs in their budgets must include a copy of the current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency. This is optional for applicants that have not included indirect costs in their budgets.

#### **Budget Narrative/Justification - Sample Format**

NOTE: Applicants requesting funding for a multi-year grant program are REQUIRED to provide a detailed Budget Narrative/Justification for EACH potential year of grant funding requested.

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
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Personnel	\$47,700	\$23,554	\$0	\$71,254	<p><b>Federal</b>          Project Director (name) = .5 FTE @ \$95,401/yr = \$47,700</p> <p><b>Non-Fed Cash</b>          Officer Manager (name) = .5FTE @ \$47,108/yr = \$23,554</p> <p><b>Total</b>          71,254</p>
Fringe Benefits	\$17,482	\$8,632	\$0	\$26,114	<p><b>Federal</b>          Fringe on Project Director at 36.65% = \$17,482          FICA (7.65%)          Health (25%)          Dental (2%)          Life (1%)          Unemployment (1%)</p> <p><b>Non-Fed Cash</b>          Fringe on Office Manager at 36.65% = \$8,632          FICA (7.65%)          Health (25%)          Dental (2%)          Life (1%)          Unemployment (1%)</p>
Travel	\$4,707	\$2,940	\$0	\$7,647	<p><b>Federal</b>          Local travel: 6 TA site visits for 1 person          Mileage: 6RT @ .585 x 700 miles \$2,457          Lodging: 15 days @ \$110/day \$1,650          Per Diem: 15 days @ \$40/day \$600          Total          \$4,707</p> <p><b>Non-Fed Cash</b>          Travel to National Conference in (Destination) for 3 people          Airfare 1 RT x 3 staff @ \$500 \$1,500          Lodging: 3 days x 3 staff @ \$120/day \$1,080          Per Diem: 3 days x 3 staff @ \$40/day \$360          Total          \$2,940</p>

Equipment	\$10,000	\$0	\$0	\$10,000	No Equipment requested OR: Call Center Equipment Installation = \$5,000 Phones = \$5,000 Total \$10,000
Supplies	\$3,700	\$5,670	\$0	\$9,460	<b>Federal</b> 2 desks @ \$1,500 \$3,000 2 chairs @ \$300 \$600 2 cabinets @ \$200 \$400 <b>Non-Fed Cash</b> 2 Laptop computers \$3,000 Printer cartridges @ \$50/month \$300 Consumable supplies (pens, paper, clips etc...) @ \$180/month \$2,160 Total \$9,460
Contractual	\$30,171	\$0	\$0	\$30,171	(organization name, purpose of contract and estimated dollar amount) Contract with AAA to provide respite services: 11 care givers @ \$1,682 = \$18,502 Volunteer Coordinator = \$11,669 Total \$30,171 <i>If contract details are unknown due to contract yet to be made provide same information listed above and: A detailed evaluation plan and budget will be submitted by (date), when contract is made.</i>
Other	\$5,600	\$0	\$5,880	\$11,480	<b>Federal</b> 2 consultants @ \$100/hr for 24.5 hours each = \$4,900 Printing 10,000 Brochures @ \$.05 = \$500

					Local conference registration fee (name conference) = \$200 Total \$5,600
					<b>In-Kind Volunteers</b> 15 volunteers @ \$8/hr for 49 hours = \$5,880
Indirect Charges	\$20,934	\$0	\$0	\$20,934	21.5% of salaries and fringe = \$20,934 IDC rate is attached.
<b>TOTAL</b>	<b>\$140,294</b>	<b>\$40,866</b>	<b>\$5,880</b>	<b>\$187,060</b>	

### Budget Narrative/Justification - Sample Template

NOTE: Applicants requesting funding for a multi-year grant program are REQUIRED to provide a detailed Budget Narrative/Justification for EACH potential year of grant funding requested.

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Personnel					
Fringe Benefits					
Travel					
Equipment					
Supplies					
Contractual					
Other					
Indirect Charges					
<b>TOTAL</b>					

### Project Work Plan - Sample Template

NOTE : Applicants requesting funding for a multi-year grant program are REQUIRED to provide a Project Work Plan for EACH potential year of grant funding requested.

Goal:

Measurable Outcome(s):

\* Time Frame (Start/End Dates by Month in Project Cycle)

Major Objectives	Key Tasks	Lead Person	1*	2*	3*	4*	5*	6*	7*	8*	9*	10*	11*	12*
1.														
2.														
3.														

4.												
5.												
6.												

NOTE: Please do note infer from this sample format that your work plan must have 6 major objectives. If you need more pages, simply repeat this format on additional pages.

### Instructions for Completing the Project Summary/Abstract

- All applications for grant funding must include a Summary/Abstract that concisely describes the proposed project. It should be written for the general public.
- To ensure uniformity, limit the length to 265 words or less, on a single page with a font size of not less than 11, doubled-spaced.
- The abstract must include the project's goal(s), objectives, overall approach (including target population and significant partnerships), anticipated outcomes, products, and duration. The following are very simple descriptions of these terms, and a sample Compendium abstract.

**Goal(s)** – broad, overall purpose, usually in a mission statement, i.e. what you want to do, where you want to be.

**Objective(s)** – narrow, more specific, identifiable or measurable steps toward a goal. Part of the planning process or sequence (the “how”) to attain the goal(s).

**Outcomes** - measurable results of a project. Positive benefits or negative changes, or measurable characteristics that occur as a result of an organization's or program's activities. (Outcomes are the end-point)

**Products** – materials, deliverables.

- A model abstract/summary is provided below:

The Delaware Division of Services for Aging and Adults with Physical Disabilities (DSAAPD), in **partnership** with the Delaware Lifespan Respite Care Network (DLRCN) and key stakeholders will, in the course of this two-year project, expand and maintain a statewide coordinated lifespan respite system that builds on the infrastructure currently in place. The **goal** of this project is to improve the delivery and quality of respite services available to families across age and disability spectrums by expanding and coordinating existing respite systems in Delaware. The **objectives** are: 1) to improve lifespan respite infrastructure; 2) to improve the provision of information and awareness about respite service; 3) to streamline access to respite services through the Delaware ADRC; 4) to increase availability of respite services.

Anticipated **outcomes** include: 1) families and caregivers of all ages and disabilities will have greater options for choosing a respite provider; 2) providers will demonstrate increased ability to provide specialized respite care; 3) families will have streamlined access to information and satisfaction with respite services; 4) respite care will be provided using a variety of existing funding sources and 5) a sustainability plan will be developed to support the project in the future. The expected **products** are marketing and outreach materials,

caregiver training, respite worker training, a Respite Online searchable database, two new Caregiver Resource Centers (CRC), an annual Respite Summit, a respite voucher program and 24/7 telephone information and referral services.

## **Instructions for Completing the "Supplemental Information for the SF-424" Form**

**1. Project Director.** Name, address, telephone and fax numbers, and e-mail address of the person to be contacted on matters involving this application. Items marked with an asterisk (\*) are mandatory.

**2. Novice Applicant.** Select "Not Applicable To This Program."

**3a. Human Subjects Research.** Check "No" if research activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of Item 3 are then not applicable. Check "Yes" if research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution. Check "Yes" even if the research is exempt from the regulations for the protection of human subjects.

**3b. Human Subjects Research.** Check "Yes" if all the research activities proposed are designated to be exempt from the regulations. Check the exemption number(s) corresponding to one or more of the six exemption categories listed in I. B. "Exemptions." In addition, follow the instructions in II. A. "Exempt Research Narrative" below. Check "No" if some or all of the planned research activities are covered (not exempt). In addition, follow the instructions in II. B. "Nonexempt Research Narrative" in the attached page entitled "Definitions for U.S. Department of Education Supplemental Information for the SF-424."

**3b. Human Subjects Assurance Number.** If the applicant has an approved Federal Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, that covers the specific activity, insert the number in the space provided. (**A list of current FWAs is available at:** <http://ohrp.cit.nih.gov/search.aspx?styp=bsc>) If the applicant does not have an approved assurance on file with OHRP, enter "None." In this case, the applicant, by signature on the SF-424, is declaring that it will proceed to obtain the human subjects assurance upon request by the designated NIDILRR official. If the application is recommended/selected for funding, the designated NIDILRR official will request that the applicant obtain the assurance within 30 days after the specific formal request.

**3c. Human Subjects Narratives.** If applicable, please attach your "Exempt Research" or "Nonexempt Research" narrative to your submission of the Supplemental Information for the SF-424 form as instructed in item II, "Instructions for Exempt and Nonexempt Human Subjects Research Narratives," below.

**Note about Institutional Review Board Approval.** NIDILRR does not require certification of Institutional Review Board approval with the application. However, if an application that involves non-exempt human subjects research is recommended/selected for funding, the designated NIDILRR official will request that the applicant obtain and send the certification to NIDILRR within 30 days after the formal request. **No covered human subjects research can be conducted until the study has NIDILRR clearance for protection of human subjects in research.**

### **I. Definitions and Exemptions**

#### **A. Definitions.**

##### **—Research**

"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Activities which meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes. For

example, some demonstration and service programs may include research activities.

### —Human Subject

"a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." *(1) If an activity involves obtaining information about a living person by manipulating that person or that person's environment, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met. (2) If an activity involves obtaining private information about a living person in such a way that the information can be directly or indirectly linked to that individual, the definition of human subject is met.*

### B. Exemptions.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories of *exemptions* are not covered by the regulations:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. *If an educational practice is being introduced to the site and is not widely used for similar populations, it is not covered by this exemption.*
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. *If the subjects are children, exemption 2 applies only to research involving educational tests and observations of public behavior when the investigator(s) do not participate in the activities being observed. Exemption 2 does not apply if children are surveyed or interviewed or if the research involves observation of public behavior and the investigator(s) participate in the activities being observed. [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]*
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. *[This exemption applies only to retrospective studies using data collected before the initiation of the research.]*
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. *[The standards of this exemption are rarely met because it was designed to apply only to specific research conducted by the Social Security Administration and some Federal welfare benefits programs.]*

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## **II. Instructions for Exempt and Nonexempt Human Subjects Research Narratives.**

If the applicant marked “Yes” for Item 3.b. of the Supplemental Information for the SF 424, the applicant must attach a human subjects “exempt research” or “nonexempt research” narrative to the Supplemental Information for the SF-424 form. If you have multiple projects and need to provide more than one narrative, be sure to label each set of responses as to the project they address.

### **A. Exempt Research Narrative.**

If you marked “Yes” for item 3.b. and designated exemption numbers(s), attach the “exempt research” narrative to the Supplemental Information for the SF-424. The narrative must contain sufficient information about the involvement of human subjects in the proposed research to allow a determination by NIDILRR that the designated exemption(s) are appropriate. The narrative must be succinct.

### **B. Nonexempt Research Narrative.**

If you marked “No” for item 3.b. you must attach the “nonexempt research” narrative to the Supplemental Information for the SF-424. The narrative must address the following seven points. Although no specific page limitation applies to this section of the application, be succinct.

**(1) Human Subjects Involvement and Characteristics:** Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

**(2) Sources of Materials:** Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

**(3) Recruitment and Informed Consent:** Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

**(4) Potential Risks:** Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

**(5) Protection Against Risk:** Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

**(6) Importance of the Knowledge to be Gained:** Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be

expected to result.

(7) **Collaborating Site(s):** If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.